



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 11 1999

4668 '99 MAY 12 P1:48

The Honorable Slade Gorton
United States Senate
Washington, D.C. 20510-4701

Dear Senator Gorton:

Thank you for your letter of April 21, 1999, on behalf of the West Coast shellfish industry, concerning the petition for a performance standard for *Vibrio vulnificus* in shellfish filed with the Food and Drug Administration (FDA or the Agency) by the Center for Science in the Public Interest. FDA published a request for comments on this petition in the Federal Register of January 21, 1999.

You provided several comments on the process of establishing policies and regulations for shellfish and the need for further research in establishing scientifically sound environmental parameters for *Vibrio vulnificus* and *Vibrio parahaemolyticus*.

Thank you for your thoughtful comments. We have entered them into the Administrative Record for this petition and they will be considered in the Agency's deliberations on this petition.

We hope this information is helpful. If we may be of further assistance, please contact us.

Sincerely,

Melinda K. Plaisier
Interim Associate Commissioner
for Legislative Affairs

cc: HFA-305 (Docket No 98P-0504)

98P-0504

ANS2

SLADE GORTON
WASHINGTON

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United States Senate

WASHINGTON, DC 20510-4701

COMMITTEES:
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April 21, 1999

Dr. Patricia S. Schwartz
Center for Food Safety and Applied Nutrition
(HFS-401)
Food and Drug Administration
200 C. St. SW
Washington, D.C. 20204

Re: Performance Standard for *Vibrio Vulnificus*; Request for Comments
Department of Health and Human Services
Food and Drug Administration
[Docket No. 98P-0504]

Dear Dr. Schwartz:

These comments are being submitted in regards to the FDA's Request for Comments on performance standards for *Vibrio vulnificus* and *Vibrio parahaemolyticus*.

My comments are in regard to the process of establishing policies and regulations for shellfish and the need for further discussion and research in establishing scientifically sound environmental parameters for *Vibrio vulnificus* and *Vibrio parahaemolyticus*.

The West Coast shellfish industry has expressed concern with protecting public health and has been working via the Interstate Shellfish Sanitation Conference (ISSC) to establish significantly stricter standards and enhance data collection and research. While the West Coast growers have experienced frustration with the Gulf Coast's response to *Vibrio parahaemolyticus*, they still believe the ISSC process provides the most democratic solution to the many complex issues related to shellfish safety.

On the West Coast, where *Vibrio parahaemolyticus* has been a problem during the past two uncommonly warm summers, the shellfish industry worked with their regulators to develop a control plan. That plan, put into place this past summer, appears to have been effective in reducing illnesses caused by the bacteria. Since the plan also calls for data collection, while evidently reducing illnesses simultaneously, it would appear a logical course of action to continue using the plan through the next two summers to better assess the situation.

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Dr. Patricia S. Schwartz
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In addition, *Vibrio vulnificus* has not been detected in West Coast stocks. With that in mind, I am concerned about the pairing of *Vibrio vulnificus* and *Vibrio parahaemolyticus* as a means for banning sales of raw shellfish. It would appear that the West Coast shellfish industry would be severely impacted if a Gulf Coast organism was cited as the purpose of a national ban.

I appreciate the opportunity to comment on this issue. It is my sincere hope that the concerns of the West Coast shellfish industry will be taken into consideration when establishing this rule.

Sincerely,

A handwritten signature in black ink, appearing to read "Slade Gorton", with a stylized flourish at the end.

SLADE GORTON
United States Senator

SG:law